| Date Mailell: October 17, 2001 |
|--------------------------------|
|                                |

| •        |            |           |
|----------|------------|-----------|
| ORMATION | DISCLOSURE | STATEMENT |

## IN AN APPLICATION

(Use several sheets if necessary)

| Docket Number: |
|----------------|
| 11660 7311001  |

Application Number: 09/872,702

Sheet 1 of 6

Applicant: KOREN ET AL.

Filing Date: JUNE 1, 2001

Group Art Unit: 4632

| d647         |            |            |
|--------------|------------|------------|
| <b>367.1</b> | -11/1      | 7          |
|              | <u>964</u> | $z \simeq$ |
|              | 8          | I          |

|   |                          |                   | U.S. PATENT DOCUMEN                                     | ITS                  |          |       | 290               |
|---|--------------------------|-------------------|---|----------------------|----------|-------|-------------------|
| EXAMINER<br>INITIAL   | DOCUMENT NO.             | DATE              | NAME  | CLASS                | SUBCLASS |       | G DATE<br>OPRIATE |
| 12  | 4179,337                 | 12/18/1979        | Davis et al.  |                      | 7        |       |                   |
| 1   | 4,301,144                | 11/17/1981        | Iwashita et al.   |                      | 7        |       |                   |
|   | 4,399,216                | 08/16/1983        | Axel et al.   |                      | T        |       |                   |
|   | 4,496,689                | 01/29/1985        | Mitra   |                      |          |       |                   |
|   | 4,640,835                | 02/03/1987        | Shimizu et al.  |                      |          |       |                   |
|   | 4,657,760                | 04/14/1987        | Kung et al.   |                      |          |       |                   |
|   | 4,670,417                | 06/02/1987        | Iwasaki et al.  |                      |          |       |                   |
|   | 4,791,192                | 12/13/1988        | Nakagawa et al.   |                      | 1        |       |                   |
|   | 4,943,529                | 07/24/1990        | Van den Berg et al.                                     |                      |          |       |                   |
|   | 4,946,783                | 08/07/1990        | Beckwith et al.   |                      | 1        |       |                   |
| 1   | 5,010,182                | 04/23/1991        | Brake et al.  | 1                    |          |       |                   |
| 7   |                          | FC                | DREIGN PATENT DOCUM                                     | IENTS                |          | •     | •                 |
|   | DOCUMENT NO.             | DATE              | COUNTRY   | CLASS                | SUBCLASS | TRANS | LATION            |
|   |                          |                   |   |                      |          | YES   | NO                |
| 11  | 266710 A                 | 04/12/1989        | DD ·  |                      |          | х     |                   |
| 7   | 0 036 776                | 09/30/1981        | EP .  | ٠                    |          |       |                   |
|   | 0 073 657                | 03/09/1983        | ЕР  |                      |          |       |                   |
| V   | 0 117 058                | 08/29/1984        | EP  | <u> </u>             |          |       |                   |
|   | OTI                      | IER DOCUMEN       | TS (Including Author, Title,                            | Date, Pertinent Page | s, Etc.) |       |                   |
| J,  |                          |                   | non-radioactive assay to n<br>n assay, Jour. of Immunol |                      |          |       | ocytes: an        |
| , <u> </u>  | Altschul et al., Local A | llignment Statist | ics, Methods in Enzymolo                                | gy 266: 460-480 (    | 1996)    |       |                   |
| Altschul et al., Gapped BLAST and PSI-BLAST: a new generation of protein database search programs, Nucleic Acids Research Vol. 25, No. 17, pp. 3389-3402 (1997) |                          |                   |   |                      |          |       |                   |

23552
PATENT TRADEMARK OFFICE

**EXAMINER** 

DATE CONSIDERED

| <u> </u> |      | R      |
|----------|------|--------|
| CHILD    | 101  | C      |
| 1        | 0    | m      |
| Ō        | 6    |        |
| 2        | 1100 | $\leq$ |

FORM 1449\*

INFORMATION DISCLOSURE STATEMENT

IN AN APPLICATION
(Use several sheets if necessary)

| Docket Number: |
|----------------|
| 11660 7211901  |

Application Number: 09/872,702

Applicant: KOREN ET AL.

Filing Date: JUNE 1, 2001

Group Art Unit: 1622

34年

| No a route like     | <u> </u>  | <del></del>      |   | <u></u>            |                      | ·               | <u> </u>        |
|---------------------|---|------------------|---|--------------------|----------------------|-----------------|-----------------|
| WT & TRAU           |   |                  | U.S. PATENT DOCUMENTS                                     | S                  |                      |                 |                 |
| EXAMINER<br>INITIAL | DOCUMENT NO.                                      | DATE             | NAME  | CLASS              | SUBCLASS             |                 | DATE<br>OPRIATE |
| $\mathcal{H}$       | 5,128,529   | 07/07/1992       | Nagaoka et al.  |                    | <i>\</i> /'          |                 |                 |
|                     | 5,206,344   | 04/27/1993       | Katre et al.  |                    |                      |                 | ·               |
|                     | 5,225,212   | 07/06/1993       | Martin et al.   |                    |                      |                 |                 |
|                     | 5,364,934   | 11/15/1994 .     | Drayna et al.   |                    |                      |                 |                 |
|                     | 5,654,010   | 08/05/1997       | Johnson et al.  |                    |                      |                 |                 |
|                     | 5,821,047   | 10/13/1998 ·     | Garrard et al.  |                    |                      |                 |                 |
|                     | 5,872,215   | 02/16/1999       | Osbourne et al.   |                    |                      |                 |                 |
|                     | 5,940,307   | 08/17/1999       | Fischbarg et al.  |                    |                      |                 |                 |
| V                   | 5,969,108   | 10/19/1999       | McCafferty et al.   | 17                 |                      |                 |                 |
|                     |   | FO               | REIGN PATENT DOCUME                                       | NTS                | 7                    |                 |                 |
|                     | DOCUMENT NO.                                      | DATE             | COUNTRY   | CLASS              | SUBCLASS             | TRANS           | LATION          |
|                     |   |                  |   |                    |                      | YES             | NO              |
|                     | 0 117 060   | 08/29/1984       | EP  | -                  |                      |                 |                 |
| Ī                   | 0 139 383   | 05/02/1985       | EP  |                    |                      |                 |                 |
| 7                   | 0 183 070   | 06/04/1986       | EP  |                    |                      |                 |                 |
| Ţ,                  | 0 244 234   | 11/01/1987       | EP  |                    |                      |                 |                 |
| /                   | ОТН   | IER DOCUMEN      | TS (Including Author, Title, Da                           | te, Pertinent Page | es, Etc.)            |                 |                 |
| N                   | Andreason, Electroport<br>Methods Vol. 15, No. 2  |                  | ique for the transfer of macr                             | omolecules into    | o mammalian cell li  | nes, Tissue C   | ulture          |
| ,                   | Aplin et al., Preparation in Biochemistry, pp. 25 |                  | nd Applications of Carbohya<br>31)                        | lrate Conjugate    | es of Proteins and L | Lipids, Critica | l Review        |
|                     |   |                  | rgillus Nidulans by the Orot<br>Research Communications V |                    |                      | e Gene of New   | ırospora        |
|                     | Beach et al., <i>High-freq</i> 140-142 (1981)     | uency transform  | ation of the fission yeast Sch                            | nizosaccharomy     | ces pombe, Nature    | Vol. 290, No    | . 5802, p       |
| V                   | C. Anthony. Metabolis                             | m in the methylo | strophic yeasts, The Biochen                              | nistry of Methy    | lotrophs pp. 269-29  | 95 (1982)       |                 |

23552
PATENT TRADEMARK OFFICE

EXAMINER / Spector DATE CONSIDERED 10/31/62

| •  |                                | ==                 |       |
|--|--------------------------------|--------------------|-------|
| FORM 1449* PENFORMATION DISCLOSURE STATEMEN  | Docket Number:<br>11669.72US01 | Application Number | T     |
| IN AN APPLICATION  | Applicant: KOREN ET AL.        | N C                |       |
| IN AN APPLICATION (Use several sheets if necessary)  | Filing Date: JUNE 1, 2001      | Group Art Unit:    | $\Pi$ |
| THE ATTENDENT OF THE PARTY OF T |                                | 2001               | 7     |

|   |  | FC          | REIGN PATENT DOCUME                   | ENTS               |           | 8           |    |
|---|--|-------------|---------------------------------------|--------------------|-----------|-------------|----|
|   | DOCUMENT NO. DATE COUNTRY CLASS SUBCLASS   |             |                                       |                    | TRANS     | TRANSLATION |    |
| $\mathcal{M}$   |  |             |                                       |                    |           | YES         | NO |
|   | 0 307 247 A2   | 03/15/1989  | EP                                    | ,                  | ·,        |             |    |
|   | 0 307 247 A3 .   | 03/15/1989  | ЕР                                    |                    |           |             |    |
|   | 0 362 179 A2   | 04/04/1990  | ЕР                                    |                    |           |             | -  |
|   | 0 362 179 A3   | 04/04/1990  | EP                                    |                    |           |             |    |
|   | 0 394 538 A1   | 10/31/1990  | EP                                    |                    |           |             |    |
|   | 0 402 226 Al-  | 12/12/1990  | EP                                    |                    |           |             |    |
|   | GB 2 211 504 A   | 07/05/1989  | UK                                    |                    |           |             |    |
|   | WO 87/05330  | 09/11/1987  | PCT                                   | -                  |           |             |    |
|   | WO 89/05859  | 06/29/1989  | PCT                                   |                    |           |             |    |
|   | WO 90/13646  | 11/15/1990  | PCT                                   |                    |           |             |    |
|   | WO 91/00357  | 01/10/1991  | PCT                                   |                    |           |             |    |
|   | WO 96/07399 A1   | 03/14/1996  | PCT                                   |                    |           |             |    |
|   | WO 96/40072 A2   | 12/19/1996  | PCT                                   |                    |           |             |    |
|   | WO 96/40072 A3   | 12/19/1996  | PCT                                   | -                  |           |             |    |
|   | WO 97/03692 -  | 02/06/1997  | PCT                                   |                    |           |             |    |
| V   | WO 97/26907  | 07/31/1997  | PCT                                   | ·                  |           |             |    |
| /   | ОТ   | HER DOCUMEN | <b>TS</b> (Including Author, Title, D | ate, Pertinent Pag | es, Etc.) |             |    |
| Carter et al., Improved oligonucleotide site-directed mutagenesis using M13 vectors, Nucleic Acids Research Vol. 13, No. 12, pp. 4431-4443 (1985) |  |             |                                       |                    |           |             |    |
|   | Ca'se et al., Efficient transformation of Neurospora crassa by utilizing hybrid plasmid DNA, Proceedings of the National Academy of Sciences Vol. 76, No. 10, pp. 5259-5263 (1979) |             |                                       |                    |           |             |    |
|   | Chang et al., Pheonotypic expression in E. coli of a DNA sequence encoding for mouse dihydrofolate reductase, Nature Vol. 275, No. 5681, pp. 617-624 (1978)                        |             |                                       |                    |           |             |    |

23552
PATENT TRADEMARK OFFICE

EXAMINER Spector DATE CONSIDERED 10/31/62

EXAMINER: Initial if retarence considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.

Chothia, The Nature of the Accessible and Buried Surfaces in Proteins, Journal of Molecular Biology Vol. 105, No. 1, pp. 1-

14 (1976)

| FORM 1449*   |                 |
|--------------|-----------------|
| PE           | NFOR            |
| (o`          |                 |
| WON 0 8 50   | n E             |
| HUI 0 0      | <del>- 5/</del> |
| TENT & TRANS | ENERGY          |

NFORMATION DISCLOSURE STATEMENT

IN AN APPLICATION

(Use several sheets if necessary)

11669.72US01

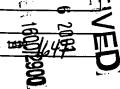
Docket Number:

Application Number: 09/872,702

Applicant: KOREN ET AL.

Filing Date: JUNE 1, 2001

Group Art Unit: 15



|     | OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)   |
|-----|--|
| M.  | Cleland, Design and Production of Single-Immunization Vaccines Using Polylactide Polyglycolide Microsphere Systems, Vaccine Design: The Subunit and Adjuvant Approach, pp. 439-462 (1995)  |
| -   | Creighton, Proteins: Structures and Molecular Principles, W.H. Freeman & Co., San Francisco, pp. 79-86 (1983)  |
| -   | Cunningham et al., High-Resolution Epitope Mapping of hGH-Receptor Interactions by Alanine-Scanning Mutagenesis, Science Vol. 244:1017-1116 (1989)   |
|     | DeBoer et al., The tac promoter: A functional hybrid derived from the trp and lac promoters, Proceedings of the National Academy of Sciences Vol. 80, No. 1, pp. 21-25 (1983)  |
|     | Edge et al., Deglycosylation of Glycoproteins by Trifluoromethanesulfonic Acid, Analytical Biochemistry Vol. 118, No. 1, pp. 131-137 (1981)  |
| -   | Fleer et al., Stable Multicopy Vectors for High-Level Secretion of Recombinant Human Serum Albumin by Kluyveromyces Yeasts, Biotechnology Vol. 9, pp. 968-975 ((1991)  |
|     | Gething et al., Cell-surface expression of influenza haemagglutinin from a cloned DNA copy of the RNA gene, Nature Vol. 293, No. 5834, pp. 620-625 (1981)  |
|     | Goeddel et al., Direct expression in Escherichia coli of a DNA sequence coding for human growth hormone, Nature, Vol. 281, No. 5732, pp. 544-548 (1979)  |
| ,   | Goeddel et al., Synthesis of human fibroblast interferon by E. coli, Nucleic Acids Research, Vol. 8, No. 18, pp. 4057-4074 (1980)  |
| ı   | Graham et al., A New Technique for the Assay of Infectivity of Human Adenovirus 5 DNA, Virology, Vol. 52, No. 2, pp. 456-467 (1973)  |
| ·   | Hess et al., Cooperation of Glycolytic Enzymes, Advances in Enzyme Regulation, Vol. 7, pp. 149-167 (1968)  |
|     | Hitzeman et al., Isolation and Characterization of the Yeast 3-Phosphoglycerokinase Gene (PGK) by an Immunological Screening Technique, The Journal of Biological Chemistry, Vol. 255, No. 24, pp. 12073-12080 (1980)                          |
|     | Holland et al., Isolation and Identification of Yeast Messenger Ribonucleic Acids Coding for Enolase, Glyceraldehye-3-phosphate Dehydrogenase, and Phosphoglycerate Kinase, Biochemistry, Vol. 17, No. 23, pp. 4900-4907 (1978)                |
| · / | Hora et al., Controlled Release of Interleukin-2 from Biodegradable Microspheres, Biotechnology, Vol. 8, pp. 755-758 (1990)  |
|     | Hsiao et al., High-frequency transformation of yeast by plasmids containing the cloned yeast ARG4 gene, Proceedings of the National Academy of Sciences, Vol. 76, No. 8, pp. 3829-3833 (1979)  |
|     | Igarashi et al., An Immunodominant Haptenic Epitope of Carbamazepine Detected in Serum from Patents Given Long-Term Treatment with Carbamazepine Without Allergic Reaction, Journal of Clinical Immunology, Vol. 12, No. 5, pp. 335-340 (1992) |

23552

PATENT TRADEMARK OFFICE

**EXAMINER** 

DATE CONSIDERED

10/31/02

| Date | Mailed: | October | 1,7, | 2001 |  |
|------|---------|---------|------|------|--|
|      |         |         |      |      |  |

| 7 |       |   |      |  |
|---|-------|---|------|--|
|   | Cheet | 5 | af 6 |  |

| Date Mailed. October 1,7, 2001              | SI SI                          | 1001 3 01 6                    | $\Xi$ | 2     |
|---|--------------------------------|--------------------------------|-------|-------|
| FORM 1449*  NFORMATION DISCLOSURE STATEMENT | Docket Number:<br>11669.72US01 | Application Number: 09/872,702 | ENTER | an An |
| Y IN AN APPLICATION                         | Applicant: KOREN ET AL.        |                                | 160   | 7     |
| Use several sheets if necessary)            | Filing Date: JUNE 1, 2001      | Group Art Unit: 1632           | 478   | Ē     |
| TATENT & TRADE NO.                          |                                |                                | 90    |       |

|   |    | OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)  |
|---|----|---|
| 1 | 1. | Johnson et al., A month-long effect from a single injection of microencapsulated human growth hormone, Nature Medicine, Vol 2, No. 7, pp. 795-799 (1996)  |
| 1 |    | Jones, Proteinase Mutants of Saccaromyces Cerevisiae, Genetics, Vol. 85, No. 1, pp. 23-33 (1977)  |
|   | _  | Kelly et al., Transformation of Aspergillus niger by the amdS gene of Aspergillus Nidulans, The Embro Journal, Vol. 4, No. 2, pp. 475-479 (1985)  |
|   | ٠, | Keown et al., Methods for Introducing DNA into Mammalian Cells, Gene Expression Technology, Vol. 185, pp. 527-537 (1990)  |
|   |    | Kingsman et al., Replication in Saccharomyces cerevisiae of plasmid pBR313 carrying DNA from the yeast trpl region, Gene, Vol. 7, No. 2, pp. 141-152 (1979)   |
|   | -  | Kyte et al., A Simple Method for Displaying the Hydropathic Character of a Protein, Journal of Molecular Biology, Vol. 157, No. 1, pp. 105-132 (1982)   |
|   | -  | Lewis, Controlled Release of Bioactive Agents from Lactide/Glycolide Polymers, Biodegradable Polymers as Drug Delivery Systems, pp. 1-41 (1990)   |
|   |    | Louvencourt et al., <i>Transformation of Kluyveromyces lactis by Killer Plasmid DNA</i> , Journal of Bacteriology, Vol. 154, No. 2, pp. 737-742 (1983)  |
|   | 1  | Mansour et al., Disruption of the proto-oncogene int-2 in mouse embryo-derived stem cells: a general strategy for targeting mutations to non-selectable genes, Nature, Vol. 336, No. 6197, pp. 348-352 (1988) |
|   | /. | Mantei et al., Rabbit $\beta$ -globin mRNA production in mouse L cells transformed with cloned rabbit $\beta$ -globin chromosomal CAN, Nature, Vol. 281, No. 726, pp. 40-46 (1979)                            |
|   |    | Mather, Establishment and Characterization of Two Distinct Mouse Testicular Epithelial Cell Lines, Biology of Reproduction, Vol. 23, No. 1, pp. 243-251 (1980)  |
|   |    | Merrifield, Solid Phase Peptide Synthesis, Journal of the American Chemical Society, Vol 85, pp. 2149-2154 (1963)   |
|   |    | Mordenti et al., The Use of Interspecies Scaling in Toxicokinestics, Toxicokinetics and New Drug Development, pp. 42-96 (1989)  |
|   | ᅱ  | Shaw et al., A general method for the transfer of cloned genes to plant cells, Gene, Vol. 23, No. 3, pp. 315-330 (1983)   |
|   | 7  | Sojar et al., A Chemical Method for the Deglycosylation f Proteins, Archives of Biochemistry and Biophysics, Vol 259, No. 1, pp. 52-57 (1987)   |
| 4 |    | Sreekrishna et al., High level expression of heterologous proteins in methylotrophic yeast, Journal of Basic Microbiology, Vol. 28, No. 4, pp. 265-278 (1988)   |



EXAMINER Species DATE CONSIDERED 10/31/02

| Yan An     | 8   |
|------------|---|
|            | Stinchcomb et al., Isolation and characterization of a yeast chromosomal replicator, Nature, Vol. 282, No. 5734, pp. 39-43 (1979)   |
| -   -      | Thotakura et al. Enzymatic Deglycosylation of Glycoproteins, Complex Carbohydrates, Vol. 138, pp. 350-359 (1987)  |
| -          | Tilburn et al., Transformation by integration in Aspergillus nidulans, Gene, Vol 26, pp. 205-221 (1983)   |
|            | Tschumper et al., Sequence of a yeast DNA fragment containing a chromosomal replicator and the TRP1 gene, Gene, Vol. 10, No. 2, pp. 157-166 (1980)  |
| -          | Urlaub et al., Isolation of Chinese hamster cell mutants deficient in dihydrofolate reductase activity, Proceedings of the National Academy of Sciences, Vol. 77, No. 7, pp. 4216-4220 (1980)   |
|            | van-Solingen et al., Fusion of Yeast Spheroplasts, Journal of Bacteriology, Vol. 130, No. 2, pp. 946-947 (1977)   |
| -          | Wells et al., Importance of hydrogen-bond formation in stabilizing the transition state of subtilisin, Philosophical Transactions of the Royal Society of London, Series A, Mathematical and Physical Sciences, Vol. 317, pp. 415-423 (1986)  |
| -          | Wells et al., Cassette Mutagenesis: an efficient method for generation of multiple mutations at defined sites, Gene, Vol. 34, pp. 315-323 (1985)  |
|            | Yelton et al., Transformation of Aspergillus nidulans by using a trpC plasmid, Proceedings of the National Academy of Sciences, Vol. 81, No. 5, pp. 1470-1474 (1984)  |
| <b>b</b> - | Zoller et al., Oligonucleotide-directed mutagenesis using M13-derived vectors: an efficient and general procedure for the production of point mutations in any fragment of DNA, Nucleic Acids Research, Vol. 10, No. 20, pp. 6487-6500 (1982) |



**EXAMINER** 

DATE CONSIDERED

10/31/02